



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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JAN 18 2002

James M. Nikrant  
President and CEO  
Lil' Drug Store Products, Inc.  
1201 Continental Place NE  
Cedar Rapids, Iowa 52402

Re: Docket No. 01P-0207/CP1

Dear Mr. Nikrant:

This letter is an interim response to the citizen petition that you submitted on April 27, 2001, on behalf of Lil' Drug Store Products, Incorporated. It is filed as CP1 in Docket No. 01P-0207 in FDA's Dockets Management Branch. The petition, which was submitted under 21 CFR 10.30, requests that the agency amend the final rule on labeling format and content requirements for over-the-counter (OTC) drug products (Drug Facts Rule). See 64 FR 13254 (March 17, 1999) (codified as 21 CFR 201.66). Specifically, the petition asks the Food and Drug Administration (FDA) to define "convenience size" OTC drug products and to modify the labeling and content requirements of the rule with respect to such products. The petition proposes that "convenience size" OTC drug products be defined as packages sold to the public that contain one or two doses of an OTC drug product.

FDA has carefully reviewed the data and information included in the petition, paying particular attention to your definition of "convenience-size" and your proposed special labeling requirements for such packages. FDA agrees that some accommodation for such packages may be appropriate, but has determined that additional comments from other interested parties should be considered before making a final decision on your petition requests. FDA is aware that a number of manufacturers, repackers, and distributors would be affected by a change to the Drug Facts Rule and would likely want to comment on our proposed course of action.

Accordingly, the agency intends to prepare, for publication in a future issue of the Federal Register, a proposed rule that would, if finalized, amend the OTC labeling rule by defining "convenience size" drug packages and addressing Drug Facts labeling requirements for such packages. The proposed rule would also provide all interested parties an opportunity to comment on the viability, desirability, and impact of the proposed amendment, and to respond to specific questions posed by the agency.

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FDA also intends to prepare, for publication in a future issue of the Federal Register, a notice that would delay the compliance date of the current Drug Facts Rule with respect to "convenience-size" drug packages. Such a delay would remain in effect until a final rule issues with respect to "convenience size" drug packages or until such time as the agency issues further notice. In either case, the delay would enable your company and other manufacturers of "convenience size" OTC drug packages to continue marketing those products in their present labeling formats pending resolution of this issue. Of course, the labeling for such packages would still have to comply with the Federal Food, Drug, and Cosmetic Act (the Act) and all other applicable regulatory requirements.

The agency is not prepared at this time to propose a precise definition of "convenience size," but our current thinking is that the definition may be a function of both the size of the OTC drug package and the number of doses contained therein.

FDA is also carefully considering which labeling format and content requirements of the Drug Facts Rule, if any, could be modified as part of a proposed amendment for "convenience size" packages. Your petition suggests that any information omitted from the outside of the package be required to appear on the inside of the package (e.g., in a package insert or on the carton labeling) so that consumers will still receive all the labeling information currently required under 21 CFR 201.66 and the Act. FDA is considering your suggestion and intends to address the particulars of any labeling modification in its proposed rule. A fundamental concern with the modification you propose is that it reduces the information available to the consumer at the point of purchase.

Finally, the agency is also considering what types of OTC drug products, if any, should be excluded from a proposed definition of "convenience size" because of health and safety concerns.

In summary, FDA intends to prepare a notice that would delay the compliance date of the current Drug Facts Rule with respect to "convenience size" products. FDA also intends to prepare a proposed amendment to the Drug Facts Rule to define "convenience-size" and to address labeling requirements for such products.

We hope this information is helpful.

Sincerely yours,



Steven Galson, M.D., MPH

Acting Director

Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1-22-02

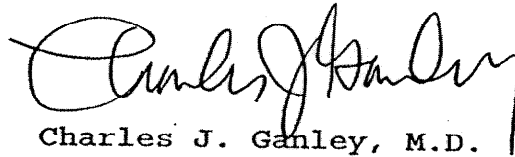
FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 01P-0207/CP1

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☒ This material should be cross-referenced to Comment No. CP1

  
Charles J. Ganley, M.D.

Attachment